

Docket No.: 0040-0168PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Annie BARDAK et al.

Application No.: 10/563,620

Confirmation No.: 1914

Filed: June 19, 2006

Art Unit: 1652

For: METHOD FOR STABILIZING A
CRYOPRECIPITATE OF PLASMATIC
PROTEINS FOR BEING SUBJECTED TO A
VIRAL INACTIVATION THERMAL
TREATMENT

Examiner: H. A. Robinson

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In the Office Action dated September 17, 2008, the Examiner has required a restriction between the claims of Group I (claims 1-19) and the claims of Group II (claims 20-21). This requirement is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1. Applicants submit, however, that the Examiner has not properly construed or applied the unity of invention standards applicable under PCT Rule 13.

Under PCT Rule 13.2, the application fulfills the unity of invention requirement when there is “a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” In the present application, the “technical

relationship” or “special technical feature” involved with both groups of inventions is the use of a formulation comprising a mixture of arginine, at least one hydrophobic amino acid, and trisodium citrate. This feature is recited in both independent claim 1 and independent claim 20. The importance of this feature is described, for example, in the summary of the invention section at pages 6-7 of the application. The Examiner has not even attempted to explain why this feature is not a “special technical feature” sufficient to provide unity of invention to both groups of claims. As such, Applicants submit that the Examiner has not explained a proper basis for objecting to unity of invention.

Secondly, the Examiner will note that no unity of invention objection was raised during the international phase of this application, which also applied the unity of invention standard under PCT Rule 13. An international application which complies with those unity of invention requirements must then be accepted by all of the designated and elected offices, including the USPTO, since article 27(1) of the Patent Cooperation Treaty does not permit any national law or national office to require compliance with different regulations relating to the contents of the international application. Thus, the U.S. application must be examined for unity of invention consistent with the Patent Cooperation Treaty. This means an actual proper application of that standard, not merely giving verbal assent to the unity of invention section of the rules. See *Caterpillar Tractor Co. v. Commission of Patents and Trademarks*, 231 USPQ 590 (E.D. VA. 1986).

For the above reasons, Applicants request that the restriction requirement be withdrawn in its entirety and all of the claims be examined in this application.

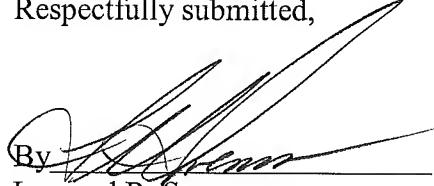
In order to be fully responsive to the Office Action, Applicants elect, with traverse, to prosecute the claims of Group I, namely claims 1-19 directed to the process.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson, Registration No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: October 17, 2008

Respectfully submitted,

A handwritten signature in black ink, appearing to read "By [Signature] Leonard R. Svensson".

Leonard R. Svensson
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